

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2839. Adulteration of thiamine hydrochloride injection, sodium salicylate and iodide with colchicine ampuls, and physiological salt solution. U. S. v. Gotham Pharmaceutical Co., Inc. Plea of guilty. Fine, \$1,500. (F. D. C. No. 24257. Sample Nos. 1001K, 66337-H, 87813-H.)

INFORMATION FILED: October 19, 1948, Eastern District of New York, against Gotham Pharmaceutical Co., Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about June 9 and 12 and August 13, 1947, from the State of New York into the States of Florida, Pennsylvania, and New Jersey.

NATURE OF CHARGE: *Thiamine hydrochloride injection* and *physiological salt solution*. Adulteration, Section 501 (b), the articles purported to be, and were represented as, drugs the names of which, "Thiamine Hydrochloride Injection" and "Physiological Salt Solution," respectively, are recognized in the United States Pharmacopoeia; and their quality and purity fell below the official standards. The standards provide that such articles must conform to the requirements for injections prescribed in the Pharmacopoeia, and the articles failed to meet those requirements for injection since they were not substantially free of undissolved material which could be detected when tested in accordance with the prescribed method; and the difference in quality and purity of the articles from the standards was not plainly stated, or stated at all, in their labeling.

Sodium salicylate and iodide with colchicine ampuls. Adulteration, Section 501 (b), the article purported to be, and was represented as, "Sodium Salicylate and Iodide with Colchicine Ampuls," the name of which is recognized in the National Formulary; and its quality and purity fell below the official standard. The standard provides that "Sodium Salicylate and Iodide with Colchicine Ampuls" must conform to the requirements for ampuls prescribed in the Formulary, whereas the article failed to meet the requirements for ampuls so prescribed since it was not substantially free from undissolved material which could be detected when tested in accordance with the prescribed method; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: February 24, 1949. A plea of guilty having been entered, the court imposed a fine of \$1,500.

2840. Adulteration and misbranding of estrogenic substances. U. S. v. 6 Vials * * *. (F. D. C. No. 27162. Sample Nos. 56162-K, 56176-K.)

LIBEL FILED: On or about April 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about January 5, 1949, by Rare Chemicals, Inc., from Harrison, N. J.

PRODUCT: 6 10-cc. vials of *estrogenic substances* at New York, N. Y.

LABEL, IN PART: (Carton) "Estrogenic Substances Rare In Sesame Oil Natural estrogenic substances in sesame oil with 3% benzyl alcohol 1 cc - 50,000 I. U. Natural Estrogenic Substances."